IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

RONNIE MORGAN,	§	
	§	
Plaintiff,	§	
	§	Civil Action No. 3:15-cv-00032
v.	§	
	§	Judge Sim Lake
MEDTRONIC PS MEDICAL, INC.,	§	
	§	
Defendant.	§	

DEFENDANT MEDTRONIC, INC.'S
RULE 12(C) MOTION FOR JUDGMENT ON THE PLEADINGS

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Regulations

Other Authorities

Pursuant to Federal Rule of Civil Procedure 12(c), Defendant Medtronic, Inc. (incorrectly named as Medtronic PS Medical, Inc.)[1] ("Medtronic" or "Defendant") files this Motion for Judgment on the Pleadings ("Motion") establishing that Plaintiff's claims are preempted under federal law and should therefore be dismissed. *See* 21 U.S.C. §§ 360k(a), 337(a). Additionally, Plaintiff's breach-of-warranty claims (Causes of Action 5 through 7) are barred because Plaintiff failed to provide pre-suit notice to Medtronic as required by Texas law.

INTRODUCTION

This is a products liability lawsuit asserting Texas state-law claims for negligence, strict liability, and breach of warranties. *See* Original Petition ("Pet.") (Dkt. # 1-1 at 4-14). Plaintiff Ronnie Morgan alleges he was injured in October 2013 by a Class III prescription, implanted medical device: the SynchroMed II Implantable Infusion System (the "SynchroMed II Pump"). The SynchroMed II Pump is implanted beneath the skin to treat certain medical conditions by delivering medication (*i.e.*, morphine sulfate or baclofen) via a catheter directly to the area where fluid flows around the spinal cord.

The Food and Drug Administration ("FDA") approved the SynchroMed II Pump under its Premarket Approval ("PMA") process – its most rigorous standard for medical devices. In light of this approval, all of Plaintiff's claims should be dismissed because they are (1) expressly preempted under 21 U.S.C. § 360k(a) (to the extent they are based on state-law) and (2) impliedly preempted under 21 U.S.C. § 337(a) (to the extent they are attempting to enforce federal law regarding the SynchroMed II Pump). Additionally, Plaintiff's breach-of-warranty claims are barred by Plaintiff's noncompliance with the pre-suit notice requirements contained in TEX. BUS. & COM. CODE § 2.607(c)(1).

[1] Medtronic PS Medical, Inc. does not manufacture or sell the device by which the Plaintiff alleges he was injured, the SynchroMed II Pump. Medtronic, Inc. – not Medtronic PS Medical, Inc. – sells the SynchroMed II Pump.

BACKGROUND

The FDA imposes strict regulations on the design, manufacture, and sale of Class III medical devices like the SynchroMed II Pump pursuant to the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). The following sections provide an overview of this regulatory regime, as well as its relationship to the state-law claims Plaintiff asserts here.

A. The Rigorous Premarket Approval Process.

The express purpose of the Medical Device Amendments is to "impose[] a regime of detailed federal oversight" over medical devices. *Riegel v. Medtronic Inc.* 552 U.S. 312, 316 (2008). Depending on the various risks involved with a device, the Medical Device Amendments create different levels of federal oversight. Class III devices like the SynchroMed II Pump are those which are used "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or which "present[] a potential unreasonable risk of illness or injury." *Id.* at 317 (quoting 21 U.S.C. § 360c(a)(1)). Given these inherent potential risks, Class III devices receive the greatest scrutiny from the FDA before they are approved for marketing.

"Premarket approval is a 'rigorous' process." *Id.* (citation omitted). It requires manufacturers to submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission. *Id.* at 317-18. After conducting a thorough cost-benefit analysis, the FDA "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* at 318 (citing 21 U.S.C. § 360e(d)). If approval is granted, "the [Medical Device Amendments] forbid[] the manufacturer to make, without FDA permission, changes in design specifications,

manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319 (citing § 360e(d)(6)(A)(i)).

The FDA's oversight of the devices continues after approval. This includes continued monitoring and regulation of how the product is manufactured, labeled, and marketed, as well as any changes in the design specifications that would affect safety or effectiveness. *Id*. at 319. Further, federal regulations prohibit the production or labeling of any device in a manner inconsistent with any conditions of approval specified in the approval order. 21 C.F.R. § 814.80. The applicant must also submit a supplemental application setting forth any proposed changes for FDA approval before implementing any such changes. 21 C.F.R. § 814.39.

In short, through the PMA process, the FDA engages in a thorough and ongoing cost-benefit analysis that weighs the potential benefits of a device against its potential risks. Via PMA review, the FDA has the final and exclusive authority over the regulation of a Class III device. To maintain this exclusive authority, the Medical Device Amendments contain an express preemption provision that states that once a Class III device receives approval, no state "may establish or continue in effect with respect to a device . . . any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." 21 U.S.C. § 360k(a). Accordingly, state-law tort claims challenging the design, manufacture, or labeling of a PMA medical device are expressly preempted by § 360k(a). *Riegel*, 552 U.S. at 321-25. The Medical Device Amendments also contain a "no private right of action" clause stating that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Thus, the FDA has the authority to investigate violations of the FDCA and its amendments, and "has at its disposal a

variety of enforcement options that allow it to make a measured response" to wrongdoing that it uncovers. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 (2001) (holding that claims based on violation of FDA regulations in the context of a PMA-approved medical device were impliedly preempted).

B. The SynchroMed II Pump Received FDA Approval Through the Rigorous PMA Process.

The SynchroMed II Pump that was implanted into Plaintiff's body is a Class III, PMA-approved medical device.[2] (Pet. ¶ 6); *see also* SynchroMed II Programmable Drug Infusion System Premarket Approval Database Listing for P860004/S056 (Ex. A).[3] The FDA approved the SynchroMed II Pump as a pump that is implanted beneath the skin to treat certain medical conditions by delivering medication (*i.e.*, morphine sulfate or baclofen) via a catheter directly to the intrathecal space, an area where fluid flows around the spinal cord. The FDA granted PMA approval to the original SynchroMed Pump & Infusion System in 1988 (*see* SynchroMed Premarket Approval Database Listing, Ex. B), and has since approved numerous supplements, which are the manufacturer's proposed changes to the original device. (*See id.*) The specific version of the device at issue here (Model 8637) received PMA approval via Supplement 56

[2] The Court may take judicial notice of the FDA's PMA documents because they are public government records that are not subject to reasonable dispute. Fed. R. Evid. 201(b); *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) ("[W]e hold that it was appropriate for the court to take judicial notice, under Rule 12(b)(6), of the PMA the FDA granted to Stryker for marketing its [medical device]."). Indeed, a court recently took judicial notice of the very same documentation that Medtronic submits with this Motion, concluding that the SynchroMed II Pump is a Class III, PMA-approved medical device. *McBride v. Medtronic, Inc.*, No. 13-377, 2013 WL 3491085, at *2 (W.D. La. July 10, 2013) ("[W]e hereby take judicial notice of the FDA information presented by Medtronic verifying that the Synchro[M]ed II [P]ump is a Class III PMA device.").

[3] All FDA documents cited herein regarding the SynchroMed II Pump are publicly accessible and can be located via the FDA's searchable database at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. The FDA does not issue static web addresses for these kinds of documents, so they can be reliably obtained from the FDA only from this searchable database.

(P860004/S056) on September 12, 2003. (Ex. A.)

As noted above, the FDA's oversight did not end upon premarket approval of the original device or the subsequent supplements. Rather, the SynchroMed II Pump continues to be subject to rigorous FDA oversight. *E.g.*, 21 C.F.R. §§ 814.39(a), 814.82, 814.84. If Medtronic does not comply with the continued PMA requirements, the FDA can, and has the exclusive authority to, enforce its requirements for the SynchroMed II Pump. *See* 21 U.S.C. §§ 337(a), 351, 352, 360(h), 374.

C. Plaintiff's Claims against Medtronic.

Plaintiff alleges that sometime prior to October 2013, a SynchroMed II Pump was implanted into his body to address his chronic pain. (Pet. ¶ 6.) On October 16, 2013, Plaintiff was allegedly admitted to Clear Lake Regional Medical Center with symptoms consistent with drug withdrawal. (*Id*. ¶ 7.) Plaintiff alleges his pump malfunctioned by failing to provide a warning "that the pump no longer had morphine in it," and as a result, "Plaintiff unknowingly went through morphine withdrawal symptoms." (*Id*. ¶¶ 8-9.) A week later, Plaintiff's SynchroMed II Pump was allegedly explanted and replaced. (*Id.* ¶ 10.) Plaintiff contends he suffered "permanent injuries and damages" as a result of these events. (*Id*. ¶ 11.)

The Petition asserts seven Texas state-law causes of action against Medtronic: (1) negligence (*id.* ¶¶ 12-17); (2) "strict product liability – design defect" (*id*. ¶¶ 18-23); (3) "strict product liability – failure to warn" (*id.* ¶¶ 24-29); (4) "strict products liability – manufacturing defect" (*id.* ¶¶ 30-34); (5) breach of express warranty (*id.* ¶¶ 35-39); (6) breach of implied warranty of merchantability (*id.* ¶¶ 40-45); and (7) breach of implied warranty of fitness for a particular purpose (*id.* ¶¶ 46-51). Medtronic filed its Original Answer and asserted various affirmative defenses (including the defense of federal preemption) in state court on February 13, 2015. (Dkt. # 1-1 at 19-30.) Subsequently, on February 18, 2015, Medtronic removed the case

to this Court based on diversity jurisdiction. (Dkt. # 1.)

Because the device at issue in this case is a Class III PMA device, the affirmative defense of federal preemption is purely a legal matter and can be decided on the pleadings. Further, Plaintiff's failure to allege compliance with TEX. BUS. & COM. CODE § 2.607(c)(1) bars his warranty claims as a matter of law.

LEGAL STANDARD

A Rule 12(c) motion for judgment on the pleadings is evaluated under the same standard as a Rule 12(b)(6) motion to dismiss for failure to state a claim. *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 610 (5th Cir. 2014). "To avoid dismissal, a plaintiff must plead facts sufficient to state a claim for relief that is plausible on its face." *Id.* (quotation marks omitted). Although the Court must accept Plaintiff's factual allegations as true, "naked assertion[s] devoid of further factual enhancement" will not suffice. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation marks omitted). Dismissal is warranted "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct," *id.* at 679, and when the factual allegations are "so sketchy that the complaint does not provide the type of notice of the claim to which the defendant is entitled under Rule 8." *Airborne Beepers & Video, Inc. v. AT&T Mobility LLC*, 499 F.3d 663, 667 (7th Cir. 2007).

ARGUMENTS AND AUTHORITIES

In 2008, in a case very similar to this case, the United States Supreme Court confirmed that the Medical Device Amendments to the FDCA create an exclusive federal regulatory framework for ensuring the safety and effectiveness of Class III PMA medical devices, governed by the FDA. *Riegel*, 552 U.S. 312; *see also* 21 U.S.C. § 360k(a). Under *Riegel*'s straightforward reading of the FDCA, states may not enforce standards against PMA medical devices that are different from or additional to that which the federal government imposes. This

is known as "express preemption," because it is based on the express language of the statute. In addition, any state-law claims premised solely on violations of federal regulations are impliedly preempted, as the Supreme Court confirmed in *Buckman*, 531 U.S. at 348-49. Implied preemption rests on the principle that the federal government – not private litigants – has sole authority to enforce FDA regulations. *Id.*

Courts around the country have applied the doctrines of express and implied preemption, as explained in *Riegel* and *Buckman* respectively, in dismissing claims regarding Medtronic's design, manufacturing, and labeling of various SynchroMed pumps. Many of these courts have granted dismissal at the pleading stage. *See, e.g., Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582 (E.D.N.Y. 2009) (dismissing claims against a SynchroMed pump at the pleading stage); *Carlson v. Medtronic, Inc.*, No. 3:13-cv-687-WHB-RHW (Doc. No. 19) (S.D. Miss. Aug. 28, 2014) (same); *McBride v. Medtronic, Inc.*, No. 13-377, 2013 WL 3491085 (W.D. La. July 10, 2013) (same); *Cenac v. Hubbell*, No. 09-3686, 2010 WL 4174573 (E.D. La. Oct. 21, 2010) (same); *see also Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012) (affirming summary judgment on claims against a Medtronic SynchroMed pump).

The same result has been obtained in cases involving other PMA-approved medical devices, many of which were decided within the past year. *See, e.g., Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 707 (S.D. Tex. 2014) (strict liability claim preempted whether based on design, manufacturing, or warning defects); *Zaccarello v. Medtronic, Inc.*, --- F. Supp. 2d ---, 2014 WL 3866607, at *3-4 (W.D. Mo. Aug. 6, 2014) (failure to warn, design defect, and manufacturing defect claims preempted); *Martin v. Medtronic, Inc.*, --- F. Supp. 2d ---, 2014 WL 3635292, at *10-15 (D. Ariz. July 23, 2014) (failure to warn, design defect, and negligence

claims preempted); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1040-41 (D. Haw. 2014) (same).

Likewise, federal and state courts in Texas have applied express and implied preemption in dismissing claims similar to Plaintiff's brought against other medical device manufacturers – often at the pleading stage. *See, e.g.*, *Rodriguez v. Am. Medical Sys., Inc.*, --- Fed. Appx. ---, 2014 WL 7399048 (5th Cir. Dec. 31, 2014) (affirming summary judgment on strict-liability and DTPA claims based on express preemption); *Funk v. Stryker Corp.*, 631 F.3d 777, 781-82 (5th Cir. 2011) (affirming Rule 12(b)(6) dismissal, on express preemption grounds, of strict-liability, negligence, and statutory claims brought under Texas law); *DeLeon v. Johnson & Johnson*, No. C-11-177, 2011 WL 2618957, at *2-3 (S.D. Tex. July 1, 2011) (same); *Timberlake v. Synthesis Spine, Inc.*, No. V-08-04, 2011 WL 711075, at *8-11 (S.D. Tex. Feb. 18, 2011) (granting summary judgment based on express and implied preemption); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 657-60 (S.D. Tex. 2010) (all claims dismissed at pleading stage based on express and implied preemption); *Baker v. St. Jude Med., S.C., Inc.*, 178 S.W.3d 127, 133-39 (Tex. App.—Houston [1st Dist.] 2005, pet. denied) (affirming summary judgment based on express and implied preemption).

As in these cases, and as discussed below, the Texas state-law tort claims Plaintiff asserts in his Petition are both expressly and impliedly preempted and therefore must be dismissed.

I. Plaintiff's Claims Are Expressly Preempted By Federal Law.

The Medical Device Amendments "swept back some state obligations and imposed a regime of detailed federal oversight" on medical device manufacturers. *Riegel*, 552 U.S. at 316. To further its goal of federal oversight in this area, Congress protected medical device manufacturers from differing state requirements by adopting 21 U.S.C. § 360k(a), which expressly preempts any state law that is "different from, or in addition to" the FDA's

requirements. *See also Walker*, 670 F.3d at 578 (the Medical Device Amendments "provide[] a rigorous, comprehensive, and exclusive framework that precludes state law tort claims that seek to impose different or higher standards upon federally approved devices."). Thus, state-law tort claims challenging the design, manufacture, or labeling of a PMA medical device are expressly preempted by § 360k(a). *Riegel*, 552 U.S. at 321-25. Although this leaves some injured individuals without judicial recourse, the Supreme Court found that this is required by the statute and is justified because, absent express preemption, many more individuals "would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." *Riegel*, 552 U.S. at 326.

This Court must conduct a two-step process to determine if Plaintiff's claims are expressly preempted under § 360k(a). *Id*. at 321-22. ***First***, it must "determine whether the Federal Government has established requirements applicable to" the medical device at issue. *Id*. ***Second***, if so, the Court then must determine whether Plaintiff's claims "are based upon [state law] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id*. at 322 (citing § 360k(a)). When these two conditions are established, the claims at issue are expressly preempted. *Id*.

A. Step 1: The SynchroMed II Pump is Subject to Federal Requirements.

The first step of the express-preemption test articulated in *Riegel* is indisputably satisfied. Plaintiff agrees that the device at issue is a "Medtronic SynchroMed programmable intrathecal pump" with serial number NGP379073H (Pet. ¶ 6), and there can be no dispute that the SynchroMed II Pump is a Class III, PMA-approved medical device. (Exs. A, B.)

PMA-approved Class III devices like the SynchroMed II Pump automatically satisfy the first step of the express-preemption test. This is because, as the Supreme Court concluded in *Riegel*, "[p]remarket approval … imposes [federal] 'requirements.'" 552 U.S. at 322-23. Class

III device manufacturers submit detailed applications for their device's approval to the FDA. Once approved, manufacturers cannot deviate from the approved specifications without FDA authorization. *Id.* at 323. Therefore, the federal government has established requirements for Mr. Morgan's medical device, and step one of the two-step express preemption test is satisfied.

B. Step 2: Plaintiff's Claims Are Based On State Law That Is Different From, Or Additional To, Federal Law.

The second step of the *Riegel* express-preemption test is also satisfied. It is well settled under the Medical Device Amendments that state common-law and statutory "duties underlying negligence, strict-liability, and implied-warranty claims" are considered "requirements . . . with respect to devices." *Riegel*, 552 U.S. at 327. Further, as discussed below, each of Plaintiff's claims alleges that the SynchroMed II Pump was somehow defective or unreasonably dangerous, thus satisfying the requirement that the claims "relate to safety and effectiveness." *Id*. at 322 (citing § 360k(a)). Finally, since *Riegel*, "courts across the country have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing-and-design-defect, to negligence *per se*." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (citations omitted). This is because such claims necessarily impose requirements different from or additional to those imposed by the FDA through the rigorous PMA process.[4]

Courts in Texas concur with this analysis. For example, in *Rodriguez v. American Medical Systems, Inc.*, No. 7:12-CV-330, 2014 WL 429431 (S.D. Tex. Feb. 4, 2014), the court dismissed Texas state-law claims against a medical device manufacturer based on strict liability and the Texas Deceptive Trade Practices Act under the express preemption provision of §

[4] Section 360k(a) leaves a narrow gap through which state-law claims may avoid express preemption if they are "premised on a violation of FDA regulations," because such claims merely "parallel" – rather than add to – federal requirements. *Riegel*, 552 U.S. at 330. Here, however, Plaintiff asserts no such claims.

360k(a). *Id.* at *5-7. The court noted that the plaintiff "fail[ed] to plead or otherwise explain how he has premised this claim on the violation of an applicable federal requirement." *Id.* at *6. The Fifth Circuit recently affirmed the district court's decision in its entirety. *Rodriguez v. Am. Medical Sys., Inc*., --- Fed. Appx. ---, 2014 WL 7399048 (5th Cir. Dec. 31, 2014).

Similarly, in *DeLeon*, the court applied express preemption to claims brought against a device manufacturer for, *inter alia*, products liability and negligence. 2011 WL 2618957, at *3. As in *Rodriguez*, the court concluded that these claims – which mirror those pled by Plaintiff here – "seek to impose different or additional state duties and are expressly preempted." *Id.* Texas state courts – including the Texas Supreme Court – have followed suit as well. *E.g.*, *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376-77 (Tex. 1998) (affirming summary judgment on claims against device manufacturer brought under Texas law based on express preemption); *Baker*, 178 S.W.3d at 133-39 (same).

As shown below, each of Plaintiff's state-law claims here would impose standards related to device safety and effectiveness that are different from, or in addition to, those required by the FDA. Judgment on the pleadings is therefore proper. *See Riegel*, 552 U.S. at 322-23.

i. Plaintiff's "strict liability" claims are expressly preempted.

Causes of Action 2, 3, and 4 of Plaintiff's Petition assert strict-liability claims in which he alleges that his injuries were caused by Medtronic placing into the stream of commerce an "unreasonably dangerous" and "defective" product. (Pet. ¶¶ 21, 28, 32.) In particular, Plaintiff alleges that the SynchroMed II Pump he received was unsafe based on design defects (*id.* ¶¶ 18-23), failure to warn (*id.* ¶¶ 24-29), and manufacturing defects (*id.* ¶¶ 30-34).

In Texas, strict-liability product defect claims are governed by Section 402A of the Restatement (Second) of Torts, which imposes liability upon those who sell unreasonably dangerous products that reach the user without substantial change in their condition and cause

the user physical harm. *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997). A product may be "unreasonably dangerous" due to defects in marketing, design, or manufacturing. *Id.* A marketing defect exists if the defendant "knows or should have known of a potential risk of harm presented by a product but markets it without adequate warning of the danger or providing instructions for safe use." *Ritz Car Wash, Inc. v. Kastis*, 976 S.W.2d 812, 814 (Tex. App.—Houston [1st Dist.] 1998, pet. denied). By contrast, a design defect requires that "(1) there was a safer alternative; (2) the safer alternative would have prevented or significantly reduced the risk of injury, without substantially impairing the product's utility; and (3) the safer alternative was both technologically and economically feasible when the product left the control of the manufacturer." *Smith v. Aqua-Flo, Inc.*, 23 S.W.3d 473, 477 (Tex. App.—Houston [1st Dist.] 2000, pet. denied). A manufacturing defect exists if the product's "construction or quality deviates from the specifications or planned output in a way that is unreasonably dangerous." *Torrington Co. v. Stutzman*, 46 S.W.3d 829, 844 (Tex. 2000).

These standards reveal that Plaintiff's strict-liability claims seek to impose different or additional requirements than those imposed by the FDA, and are therefore expressly preempted under *Riegel*. For example, a design defect claim necessarily requires Plaintiff to prove that Medtronic should have used an alternative design – a design different from that approved by the FDA through the PMA process. Such a claim "disrupts the federal scheme" for regulating Class III medical devices by requiring such devices to be "safer, but hence less effective, than the model the FDA has approved." *Riegel*, 552 U.S. at 325. Indeed, Cause of Action 2 alleges that "a safer alternative design was available" that would have prevented Plaintiff's injuries. (Pet. ¶ 20.) Likewise, to prevail on a failure-to-warn claim, Plaintiff would have to prove that Medtronic should have provided different or additional warnings from those approved by the

FDA. *Id.* at 329. Finally, Plaintiff's manufacturing defect claim is preempted because it would require Plaintiff to prove that his SynchroMed II Pump "deviates from the specifications or planned output" approved by the FDA, notwithstanding the fact that Plaintiff has not alleged how his SynchroMed II Pump deviated from the FDA pre-market approved plans. *Torrington*, 46 S.W.3d at 844; *Riegel*, 552 U.S. at 328.

As discussed above, both the United States Supreme Court and Texas courts acknowledge that strict-liability claims brought under state law impose requirements that are "different from, or in addition to," those imposed by the FDA through the PMA process. 21 U.S.C. § 360k(a)(1). As a result, Medtronic is entitled to judgment in its favor on Plaintiff's strict-liability claims based on express preemption.

ii. Plaintiff's negligence claim is expressly preempted.

Plaintiff also asserts a common-law negligence claim against Medtronic. In Cause of Action 1, Plaintiff contends that Medtronic acted negligently by "fail[ing] to exercise reasonable care in the design, manufacture, testing, marketing, distribution, testing and placement of the pump." (Pet. ¶ 15.) In particular, Medtronic allegedly either (1) failed to design the pump with an alarm to alert the patient when the pain medication ran low, (2) failed to incorporate such an alarm into Plaintiff's pump, or (3) provided Plaintiff with a pump with a faulty alarm. (*Id.*) Medtronic "continued to market the pain pump as safe" despite these purported failures. (*Id.* ¶ 16.) Plaintiff further claims that Medtronic "failed to perform adequate testing and evaluations of the pump prior to placing the pump into the stream of commerce." (*Id.* ¶ 14.)

Texas law treats negligent design and manufacturing claims as "conceptually distinguishable" from strict liability claims. *Grinnell*, 951 S.W.2d at 437. Such claims focus on "'the acts of the manufacturer and determine[] if it exercised ordinary care in design and production,'" and "are predicated on the existence of a safer alternative design for the product."

Id. (quoting *Caterpillar, Inc. v. Shears*, 911 S.W. 2d 383, 384 (Tex. 1995)). The claims fail as a matter of law in the absence of such an alternative design. *Id.*

As explained above, any cause of action that requires proof of a safer alternative design imposes requirements "different from, or in addition to," those imposed by the FDA through the PMA process. 21 U.S.C. § 360k(a)(1). Plaintiff's claim that Medtronic acted negligently in failing to provide a product with some other type of alarm (Pet. ¶ 15) is just such a claim: it necessarily asserts that, nothwithstanding compliance with the FDA pre-market approved design and specifications, Medtronic should have taken another approach in designing and manufacturing the SynchroMed II Pump. Therefore, Plaintiff's negligence claim – like his strict-liability claims – is expressly preempted. *Riegel*, 552 U.S. at 324-25; *DeLeon*, 2011 WL 2618957, at *3.

iii. Plaintiff's warranty claims are expressly preempted.

Finally, Plaintiff asserts claims for breach of express warranty (Cause of Action 5) and breach of implied warranties (Causes of Action 6 and 7) in which he again argues the SynchroMed II Pump is not safe and effective. Regarding the former, he alleges that Medtronic "expressly warranted that [the SynchroMed II Pump] was safe for use in the body of its users," but "did not conform to these express representations thereby giving rise to Plaintiff's injuries and damages." (Pet. ¶¶ 37-38.) On his claim for breach of the implied warranty of merchantability, Plaintiff similarly asserts that Medtronic "impliedly warranted the pain pump to be of merchantable quality and safe for its intended use and that Plaintiff relied on that warranty, but in reality, the device's purported defects rendered it unreasonably dangerous and unfit for its intended use. (*Id.* ¶¶ 42-44.) Further, Plaintiff alleges that despite Medtronic's alleged assurances, the SynchroMed II Pump "was not fit for its particular purpose, as it was unreasonably dangerous as described above." (*Id.* ¶ 50.)

In Texas, "[s]uccessful assertion of breach of an express warranty requires: 1) an affirmation or promise made by the seller to the buyer; 2) that such affirmation or promise was part of the basis for the bargain, e.g. that the buyer relied on such affirmation or promise in making the purchase; 3) that the goods failed to comply with the affirmation or promise; 4) that there was financial injury; and 5) that the failure to comply was the proximate cause of the financial injury to the buyer." *Lindemann v. Eli Lilly & Co.*, 816 F.2d 199, 202 (5th Cir. 1987) (citing *Gen. Supply & Equip. Co. v. Phillips*, 490 S.W. 2d 913, 917 (Tex. Civ. App.—Tyler 1972, writ ref'd n.r.e.)); *see also* TEX. BUS. & COM. CODE § 2.313. A claim for breach of the implied warranty of merchantability requires "pro[of] there was some defect in the product, that is to say, a condition of the goods that renders them unfit for the ordinary purpose to which they are used," *Scott v. Dorel Juvenile Grp.*, 456 Fed. Appx. 450, 456 (5th Cir. 2012) (unpublished). A claim for breach of the implied warranty of fitness for a particular purpose requires proof that "(1) the seller had reason to know any particular purpose for which the goods were required at the time of contracting and (2) the buyer was relying on the seller's skill or judgment to select or furnish suitable goods." *Bass v. Stryker Corp.*, 669 F.3d 501, 516 (5th Cir. 2012) (quotation marks omitted). *See also* TEX. BUS. & COMM. CODE §§ 2.314-15.

The Petition's factual allegations are clear: Plaintiff's breach-of-warranty claims assert that Plaintiff's SynchroMed II Pump was not safe and effective. In Plaintiff's own words, the pump was purportedly "not of merchantable quality or safe for its intended use." (Pet. ¶ 44; *see also id.* ¶¶ 37-38, 50 (alleging that the SynchroMed II Pump was unsafe and unreasonably dangerous).) Thus, as with Plaintiff's defect claims, the warranty claims are necessarily predicated on a finding that runs contrary to the FDA's conclusive determination, via the PMA process, that there is "a 'reasonable assurance' of the device's 'safety and effectiveness.'"

Riegel, 552 U.S. at 318 (quoting 21 U.S.C. § 360e(d)). Because Plaintiff's warranty claims would impose different or additional requirements pertaining to efficacy and safety on Medtronic than those imposed by the FDA's premarket approved design specifications, those claims are preempted as well. *Bass*, 669 F.3d at 515-17 (applying Texas law and dismissing claims for breach of express and implied warranties that did not adequately allege violations of FDA requirements).

II. Plaintiff's Claims Are Impliedly Preempted By Federal Law.

Even if Plaintiff did allege that his injuries were somehow caused by Medtronic's violation of an FDA requirement (which, as noted above, Plaintiff does not do), his claims would still be barred by implied preemption. Applied by the Supreme Court in *Buckman*, this doctrine is premised on the fact that the federal government has sole authority to enforce the requirements imposed by the FDCA.

Federal law provides that all actions to enforce the FDCA's requirements, including those imposed by the FDA through the PMA process, must be undertaken by the United States government only. 21 U.S.C. § 337(a) (with the exception of limited state enforcement actions (not at issue here), "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"). This is for good reason: the Supreme Court has recognized that the PMA process "involves a time-consuming inquiry into the risks and efficacy of each device." *Buckman*, 531 U.S. at 348. Allowing the use of state-law claims to enforce federal law inevitably conflicts with this federal regulatory process: "As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants – burdens not contemplated by Congress in enacting the FDCA and the [Medical Device Amendments]." *Id.* at 350.

In light of these considerations, courts in Texas and elsewhere have recognized that "private enforcement of FDCA regulations via state common law would interfere with this regulatory scheme and is therefore prohibited." *Lewkut*, 724 F. Supp. 2d at 659 (holding that plaintiff's purportedly parallel negligence, strict liability, and DTPA claims were impliedly preempted under *Buckman*); *see also, e.g.*, *In re Medtronic*, 592 F. Supp. 2d at 1161 (holding that parallel claims alleging violations of FDA requirements are impliedly preempted by 21 U.S.C. § 337(a): "[W]hen Sections 337(a) and 360k(a)—as construed in *Buckman* and *Riegel*, respectively—are read together, nearly all types of claims concerning FDA-approved medical devices are preempted").

As discussed above in Part I, Plaintiff's negligence, strict-liability, and warranty claims are barred by express preemption under § 360k(a) because they seek to impose different or additional requirements related to safety and effectiveness than those imposed by federal law through the PMA process. Moreover, even if Plaintiff attempted to connect his clams to specific federal requirements (which he does not), the claims would then be impliedly preempted under § 337(a). Although couched in state-law terms, any such claims would "exist solely by virtue of [federal law]." *Buckman*, 531 U.S. at 353. Because only the federal government can enforce the FDCA and its regulations, any claims asserting violations of federal law would conflict with the FDA's own extensive regulatory regime. Therefore, this Court should follow *Buckman*, *Lewkut*, and *Medtronic* and hold that, to the extent Plaintiff's claims are not expressly preempted under 21 U.S.C. § 360k(a), they are impliedly preempted under 21 U.S.C. § 337(a).

III. Plaintiff's Breach Of Warranty Claims (Causes of Action 5-7) Are Barred Because Plaintiff Did Not Provide Pre-Suit Notice To Medtronic.

Finally, separate and apart from preemption, dismissal is required on Plaintiff's breach-of-warranty claims because Plaintiff did not provide Medtronic with pre-suit notice of the

alleged breach, as required by Texas law.

To bring a breach of warranty claim, a plaintiff "must within a reasonable time after [s]he discovers or should have discovered any breach notify the seller of breach or be barred from remedy." TEX. BUS. & COM. CODE § 2.607(c)(1) (emphasis added). Courts in Texas consistently hold that failure to provide pre-suit notice is fatal to a plaintiff's warranty claim. *See, e.g., U.S. Tire-Tech, Inc. v. Boeran, B.V.*, 110 S.W.3d 194, 201 (Tex. App.—Houston [1st Dist.] 2003, pet. denied) (plaintiff's breach of warranty claims fail because plaintiff provided no notice to manufacturer); *Lochinvar Corp. v. Meyers*, 930 S.W.2d 182, 189 (Tex. App.—Dallas 1996, no writ) ("Failure to notify the seller of the breach . . . bars recovery on the basis of breach of warranty."); *Wilcox v. Hillcrest Mem'l Park of Dallas*, 696 S.W.2d 423, 424 (Tex. App.—Dallas 1985), *writ ref'd n.r.e. per curiam*, 701 S.W.2d 842 (Tex. 1986) (failure to provide notice "bars the buyer from any remedy for breach of warranty under the Texas Business & Commerce Code"); *Sw. Lincoln-Mercury, Inc. v. Ross*, 580 S.W.2d 2, 5 (Tex. App—Houston [1st Dist.] 1979, no writ) (defendant not liable for breach of warranty where court was "unable to ascertain whether [defendant] was given notice as prescribed by Section 2.607(c) of the Texas Business and Commercial Code"). Applying this line of authority, the Fifth Circuit recently agreed. *McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 705-07 (5th Cir. 2014) (affirming summary judgment on warranty claims based on failure to comply with Section 2.607).

The purpose of the pre-suit notice requirement is "to give the seller an opportunity to inspect the product to determine whether it was defective and to allow the seller an opportunity to cure the breach, if any." *Wilcox*, 696 S.W.2d at 424; s*ee also Amer. Mfg. Co. v. U.S. Shipping Bd. Emergency Fleet Corp.*, 7 F.2d 565 (2d Cir. 1925) (Hand, J.) (with respect to precursor to UCC § 2-607, "[t]he purpose of the notice is to advise the seller that he must meet a claim for

damages, as to which, rightly or wrongly, the law requires that he shall have early warning."). Importantly, the majority of courts – including the Fifth Circuit – hold that the requirement applies even where the manufacturer is "remote," *i.e.*, not in direct privity with the plaintiff. *McKay*, 751 F.3d at 706-07; *U.S. Tire–Tech, Inc*., 110 S.W.3d at 199; *Wilcox*, 696 S.W.2d at 424–25. Finally, filing a lawsuit does not satisfy the notice requirement. *McKay*, 751 F.3d at 706; U.*S. Tire–Tech Inc*., 110 S.W.3d at 202; *see also Wilcox*, 696 S.W.2d at 424 ("untenable" to allow plaintiff to recover for breach of warranty where remote seller "never had an opportunity to remedy the defect to [plaintiff's] satisfaction before litigation was commenced").

Further, courts in Texas and across the country have applied Section 2.607 at the pleading stage, dismissing warranty claims that fail to allege compliance with the notice requirement. *See, e.g., Durso v. Samsung Elec. Am., Inc.*, No. 12-cv-5352, 2014 WL 4237590, at *7-9 (D.N.J. Aug. 26, 2014) (granting Rule 12(b)(6) motion in part and dismissing warranty claims with prejudice); *Alvarez v. Chevron Corp.*, No. CV 09-3343-GHK (CWx), 2009 WL 5552497, at *3 (C.D. Cal. Sept. 30, 2009) (applying Section 2.607 and analogous California statute and dismissing warranty claims at pleading stage without leave to amend); *Mehler Texnologies, Inc. v. Monolithic Constructors, Inc*., No. 3:09-cv-0655-M, 2009 WL 3149383, at *4 (N.D. Tex. Sept. 29, 2009) (dismissing breach-of-warranty counterclaim at pleading stage); *In re Air Bag Prods. Liab. Litig.*, 7 F. Supp. 2d 792, 804 (E.D. La. 1998) ("Where, as here, 'there is no room for ordinary minds to differ as to the proper conclusions to be drawn from the evidence' on notice, the issue of notice is a question of law properly resolved in the context of a motion to dismiss.") (quoting *Carroll Instrument Co. v. B.W.B. Controls, Inc.*, 677 F.W.2d 654, 657 (Tex. App.—Houston [1st Dist.] 1984, no writ)).

Here, Plaintiff does not allege in his Petition (nor could he) that he complied with the pre-

suit notice requirements. Because Plaintiff did not notify Medtronic "within a reasonable time" of his belief that Medtronic breached any alleged warranty (TEX. BUS. & COM. CODE § 2.607(c)(1)), his breach-of-warranty claims should be dismissed with prejudice.

PRAYER

For the foregoing reasons, Medtronic respectfully requests that the Court grant this Motion, enter judgment on the pleadings in favor of Medtronic and against Plaintiff, dismiss the Petition and all purported causes of action set forth therein with prejudice, and award Medtronic its costs and such other relief as the Court may deem appropriate.

Dated: February 20, 2015

Respectfully submitted,

MEDTRONIC, INC.

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document has been served upon all counsel of record via the court's e-filing system if their email addresses are on file, and by email if not, on this 20th day of February, 2015.

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